III. Remarks

Applicants extend their thanks to the Examiner for the interview of October 14, 2003. No agreement was reached. However, suggestions and comments were made to further the prosecution of the case.

A. Claim Objections

Claim 8 was objected to because of the use of the word "whereby," Applicants have amended the claim to "wherein." Applicants respectfully request the Examiner remove the rejection.

B. Claim Rejections Under 35 USC §112, 1st ¶

Claims 1, 11, and 12 stand rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. The Examiner contends that the specific structure and function or method of operating a door assembly is unclear or missing. Applicants respectfully request reconsideration.

In regards to the Examiner's contention that the method of closing the door is unclear, the mechanism of the door is well explained on page 5, lines 11-26, wherein it states "[t]he closing off and opening up of the chamber can be by simple displacement of the plunger." Other possibilities include a chamber closed off by additional closing means, such as a door which automatically opens upon full withdrawal of the plunger. Accordingly, it is reasonable to conclude, that in an embodiment, the reverse is true, the door will close when the plunger is pushed back in.

Moreover, doors are very commonplace. In fact, it is hard to imagine any person who would not understand the structure and function or method of operating a door. This situation is much like what the Federal Circuit stated in ***Lockwood v. American Airlines, Inc.*** In that case, the Federal Circuit stated that the subject matter must necessarily be present in the application's specification such that one skilled in the art would recognize such a disclosure. Here, one skilled in the art recognizes the structure and function of a door.

The Federal Circuit stated, in ***Lockwood v. American Airlines, Inc.***, 107 F.3d 1565, 41 USPQ2d 1961(Fed. Cir. 1997), that"the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art ... [an] application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. ***Id.*** at 1572, 41 USPQ2d at 1966. Here, one skilled in the art would understand "a door." In fact, the specification provides disclosure at least at page 5, lines 16-26. In that section, five embodiments are described, a spring door; an automatic door; mechanical door; electronic door; and/or an optical door. Accordingly, Applicants specification does supply the disclosure necessary. Therefore, Applicants respectfully request reconsideration of the rejection in light of this response.

Especially in light of the fact that the specification specifically states "the chamber has an opening of such dimensions at the side of the plunger that when the plunger is pulled back behind the chamber ... an implant contained within the chamber will automatically fall into the plunger channel." (See Lines 12-16) and later "other means of the closing off of the chamber than just the plunger can be provided ... a

chamber closed off by an additional closing means such as a door." This indicates, in an embodiment, the door is an additional partition separating the chamber from the channel, the dimensions of which are such that it can close off the opening between the chamber and the channel."

Claims 1 and 12 stand rejected as failing to comply with the written description requirement. The Examiner contends that Applicants added new matter be the amendment adding "or manually." Applicants respectfully request reconsideration in light of this response, as the specification clearly states manual control in another section. On page 6, lines 21-25, the sentence clearly states that the plunger may be "pulled backwards." Pulled can, and often does, stand for a manual operation. Accordingly, manual operation is disclosed and the Examiner's rejection baseless.

C. Claim Rejections Under 35 USC §112, 2nd ¶

Claim 1 stands rejected as being indefinite because the Examiner contends that it is unclear whether the door is being positively recited or used as functional language. Applicants have amended the claims to broaden there scope. However, the reference to the door was removed. Accordingly, the rejection should be obviated. No estoppel should result from the amendment because the scope was broadened.

D. Claim Rejections Under 35 USC §102(b)

Claims 1, 3, 5, 7, 8, 11, and 12 stand rejected as being anticipated by US Pat. No. 5,562,613 (hereinafter referred to as the '613 patent). The Examiner contends that the

'613 patent discloses a pre-loadable implantation device comprising a needle (104), a body (16) and an elongated part, a plunger (108), the periphery of the plunger defining a channel, a chamber (104b) and a door(102,102a,104). The Examiner directs attention to Figures 3, 6-10 and the entire reference. The Examiner specifically draws attention to Figures 9 and 10 for a chamfered needle and figures 3 and 6 where the device is closed after preloading. Applicants respectfully request reconsidcration.

Reference to Column 5, lines 35-48, fully explain the differences between Applicants' claimed invention and the invention of thc '613 patent. No chamfered tip is present. The invention of the '613 patent specifically states that "[a]s driving member 16 is further advanced, ... thereby advancing piston 108 forward relative to cannula 104 (Fig. 8). As piston 108 is extended into cannula notch 104b, drug pellet 106 is pushed against the inclined distal surface 103 of cannula notch 104b by piston 108. The angled tip 108a of piston 108 and the inclined distal surface 103 of cannula notch 1204b displaces drug pellet 106 latcrally from the cannula notch 104b into the surrounding tissue 112." See Col. 5, ll. 35-43. The needle tips are not ever chamfered, they never are together. The pellet is expelled laterally as the piston 108 is pushed against the inclined distal surface 103. Accordingly, the device is completely different and no chamfering is accomplished. Therefore, Applicants respectfully request reconsideration of the rejection in light of this response.

Moreover, the device of the '613 patent has a "notch at the distal end for supporting the drug to be delivered and a cannula concentrically enclosing the piston during drug delivery (Col. 1, lines 34-36). Applicants' invention does not have a piston with a notch. Furthermore, in the device of the '613 patent, the notch is in the line of the

channel whereas Applicants' chamber (7) is located **radially** outside the channel. The ordinary meaning of radially is "of or situated like a radius," taken from Webster's New World Dictionary, Third College Edition, 1991. One of ordinary skill in the art would interpret radially in conjunction with the channel. Therefore, an interpretation, for an embodiment, would be that the chamber (7) is situated on the channel, like a radius. The device of the '613 patent does not have a chamber situated on the channel, like a radius. Accordingly, the '613 patent does not disclose Applicants' device and Applicants respectfully request reconsideration of the rejection.

Claims 1, 3, 5, 7, 8, 11, and 12 stand rejected as being anticipated by US Pat. No. 1,655,158 (hereinafter referred to as the '158 patent). The Examiner contends that the '158 patent discloses a preloadable implantation device comprising a needle, and an elongated part, a plunger, the periphery of the plunger defining a channel, a chamber and a door. The Examiner specifically directs attention to reference numbers 20, 23, and 24, along with Figures 1-10 and the entire reference. Specific reference is made to Figures 4-9 for a chamfered needle. Further, specific reference is made to Figures 4-8 for wherein the outside is closed after preloading. However, the '158 patent discloses a device different than the claimed device of Applicants' invention. Accordingly, Applicants respectfully request reconsideration of the rejection in light of this response.

The '158 patent specifically states that it is divided into three pieces; the implanter 1, the trocar 2 and the plunger 3. Accordingly, the claimed invention of the '158 patent first requires puncturing a tissue with a trocar 2, then removing trocar 2, then

inserting plunger 3, loading the implant and feeding the implant into to the space surrounded by broken tissue from the trocar 2. See the '158 patent, p. 3, left col., ll. 1-31.

Applicants' invention is completely different. Applicants' plunger is chamfered, thereby eliminating the need for a separate trocar and plunger. Applicants device may function as the trocar. See Specification, p. 7, ll. 1-7. Further, Applicants device is specifically designed to minimize tearing of the skin caused by a hollow needle. It is not apparent that the invention of the '158 patent does not tear the skin. In fact, the '158 patent specifically states that skin is torn.

In fact, the differences continue to mount. The needle 29 of the '158 patent is not hollow, as is specifically claimed by Applicants. The device of the '158 patent cannot anticipate Applicants' invention. It is completely different.

Accordingly, in light of these differences, Applicants respectfully request reconsideration of the rejection.

E. Claim Rejections Under 35 USC §103

Claims 1 and 3-8 stand rejected as being unpatentable over the '158 patent in further view of US Pat. No. 5,405,324 (hereinafter referred to as the '324 patent). The Examiner asserts that the '324 patent discloses the implanter as a hormonal implanter and concludes it would be within the level of ordinary skill in the art to combine the teachings of the '324 patent and the '158 patent because it is known to use different medications with an implanter Applicants respectfully request reconsideration in light of this response.

As stated above, the '158 patent teaches a three part implanter, does not have a hollow needle, no chamfered tip to prevent tearing, and does not disclose Applicants' invention. Accordingly, the combination of the teachings of the '158 patent and the '324 patent is not Applicants' invention. Therefore, Applicants respectfully request removal of the rejection.

Claims 1, 3-8, 11 and 12 stand rejected as being unpatentable over the '613 patent in further view of the '324 patent. The Examiner reasserts the contention that the '324 patent teaches a hormonal implanter and that it would have been obvious to one of ordinary skill in the art to combine the teachings of the '324 patent and the '613 patent because it is known to use different medications with an implanter.

However, as stated above, no chamfered tip is present on the device of the '613 patent. The tips do not coincide. Further, the chamber is not located radially outside the channel. Accordingly, the combination of the '613 patent and the '324 patent is not Applicants' invention. Therefore, Applicants respectfully request reconsideration of the rejection in light of this response.

IV. Conclusion

Applicants respectfully request reconsideration of the rejections in light of this response. The application is believed in a condition for allowance and Applicants respectfully request such action. Please call the below undersigned attorney for any assistance in securing allowance of this application and for an interview. Please charge deposit account number 02-2334 for any required fees and to credit any credits.

Sincerely,

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